

REMARKS

The present invention relates to stromal cells isolated from human adipose tissue. Claims 31-34 are currently under consideration, claims 31, 33, and 34 have been canceled herein. Upon entry of the present amendment, claim 32 is currently under consideration.

Withdrawn Rejection

Applicants acknowledge with appreciation the withdrawal of the rejection pursuant to 35 U.S.C. § 112, second paragraph in light of Applicants' amendments.

Claim Amendments

Applicants have amended claim 32 herein by canceling claim 33 and incorporating the subject matter of that claim into claim 32. Thus, no new matter has been added by way of the present invention. In addition, applicants have amended claim 32 to recite that the adipose tissue-derived stromal cell is in combination with a substance that promotes differentiation to the osteoblast lineage. Support for the present amendment can be found throughout the specification as-filed, particularly at page 6, beginning at line 14, where substances that promote the differentiation of an adipose tissue-derived stromal cell to an osteoblast lineage are described. Thus, the present amendments add no new matter.

Rejection of Claims 31-34 under 35 U.S.C. § 112, first paragraph

The Examiner has maintained the rejection of claims 31-34 under 35 U.S.C. § 112, first paragraph, for allegedly lacking written description. The Examiner remains of the opinion that the claims recite any isolated cell with the claimed properties, that the claims are not limited to a particular taxonomic species, and that the claims are essentially limitless in breadth.

To satisfy the standard for meeting the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. MPEP § 2163. Applicants have satisfied this burden. Specifically, claim 32, as presently amended, recites an isolated mammalian adipose tissue derived stromal cell in combination with specific differentiation promoting substances. In Example 2, beginning on page 13 at line 10, the specification describes a culture of isolated adipose-tissue derived stromal cells comprising

ascorbate-2-phosphate and β -glycerophosphate, which are induced to differentiate towards the osteoblast lineage. In Example 3, beginning at page 16, line 1, the specification describes a culture of adipose-tissue derived stromal cells comprising the bone morphogenic proteins osteopontin-I and morphogenic bone protein 4, and how these proteins positively affect osteoblast differentiation. Further, at numerous locations throughout the specification, Applicants describe a culture of adipose-tissue derived stromal cells comprising ascorbic acid (e.g. page 8, beginning at line 22; page 7, beginning at line 19; and, page 6, beginning at line 19). Thus, Applicants have demonstrated actual possession of the presently claimed invention, and have therefore met the written description requirement.

For the reasons stated above, Applicants respectfully submit that the rejection of claims 31-34 has been overcome or is now moot and request reconsideration and withdrawal of the present rejection.

Rejection of Claims 31-34 under 35 U.S.C. § 101

Applicants respectfully submit that the Examiner's rejection of claims 31 and 34 is rendered moot by the cancellation of those claims herein.

Obviousness Type Double Patenting Rejection

The Examiner has rejected claims 31-34 under the doctrine of obviousness type double patenting, alleging that the present claims are unpatentable over claim 1-32 of U.S. Patent 6,429,013. The Examiner argues that even though the '013 Patent would expire after any patent issuing from the present application, the obviousness type double patenting rejection is maintained to prevent possible harassment by multiple assignees.

The Examiner also argues that while the claims of the '013 Patent are not identical to the present claims, the present claims are not patently distinct from those in the '013 patent. Specifically, the Examiner argues that the claims are drawn to essentially the same compositions and cells as presently claimed.

Two different legal elements of an obviousness type double patenting rejection demonstrate the claims of the present application are not an obvious variation over the claim of the '013 Patent. The first element is that when determining if the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, *the*

disclosure of the patent may not be used as prior art. MPEP § 804 (II)(B)(1) (emphasis added). The second element is that the same analysis used for a 35 U.S.C. § 103(a) rejection is also used to analyze an obviousness-type double patenting rejection. *Id.* Thus, there must be some suggestion or motivation in the claims of the '013 patent, there must be a reasonable expectation of success in the claims of the '013 patent, and the claims of the '013 Patent must teach or suggest all of the claim limitations in the present application. This the '013 Patent fails to do.

Claims 1-32 of the '013 Patent recite compositions and methods relating to differentiating an adipose tissue-derived stromal cell into the chondrocyte lineage. There is no mention of the osteoblastic lineage. Since there is no mention of the osteoblastic lineage in the claims of the '013 Patent, there is no suggestion or motivation to modify the '013 Patent to arrive at the present invention. Without such a suggestion or motivation, there is no obviousness-type double patenting.

However, in addition to a lack of suggestion or motivation, the claims of the '013 offer no reasonable expectation of success in arriving at the present invention because chondrocytes and cells of the chondrocyte lineage are different than osteoblasts and cells of the osteoblast lineage. The claims of the '013 patent make no mention of osteoblasts or the osteoblast lineage, and therefore, offer no reasonable expectation of success and fail to teach or suggest each claim limitation. Thus, an obviousness-type double patenting rejection cannot stand.

For these reasons, Applicants respectfully submit that the obviousness-type double patenting rejection of claims 31-34 is either overcome or rendered moot. Applicants request reconsideration and withdrawal of the present rejection.

Summary

Applicants respectfully submit that each rejection of the Examiner to the claims of the present application has been overcome, and that claim 32 is now in condition for allowance. Applicants further submit that no new matter has been added by way of the present amendment. Reconsideration and allowance of the claims is respectfully requested.

Respectfully submitted,

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